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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,520

03/16/2004

Eric Leopold

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

PAPER NUMBER

3773

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,520	<b>Applicant(s)</b> LEOPOLD ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to claims filed 6/18/08.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the microcatheter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz as a matter of design choice and further in view of Ahmed (5,293,713).

Diaz teaches a device comprising the following:

- A sheath (12) in combination with a vasoocclusive device (50)
- the vasoocclusive device including an assembly of a flexible pusher member (44) and an embolic coil (50) configured to be loaded into a microcatheter (capable or being loaded into a microcatheter) for insertion into a portion of a vasculature for occluding a portion of the vasculature for use in interventional therapy and vascular surgery, the flexible pusher member having an unused segment when the flexible pusher member is loaded into the microcatheter (para. 42) the sheath comprising:
  - a hollow, elongated tubular member (12), having opposing upper and lower walls,
    - opposing side walls (12)
    - a longitudinal interior channel (14)

- a longitudinal slot (36/34) formed in the upper wall of the elongated tubular member and extending a majority of the length of elongated tubular member (para. 42), a segment of the upper wall of the elongated tubular member being without a slot (para. 42, the slit extends from the proximal end of the sheath 12 to a position intermediate the proximal and distal ends of the sheath 12) having opposing sides with inner side surfaces extending through the upper wall of the elongated tubular member leading to the interior channel (12) permitting introduction of the pusher member (44, Fig. 5) into the interior channel removal of the sheath from the pusher member (Fig. 5), the segment of the elongated tubular member without a slot remaining attached to the unused segment of the flexible pusher member to facilitate initiation of loading of the flexible pusher member into the sheath (Fig. 5)
- wherein the outside diameter is approximately .003 inches, and wherein the inside diameter is slightly greater than that of a deployment catheter (Page 4, paragraph 42), corresponding to the lower wall of the hollow, elongated tubular member (12) being about 0.002 to 0.004 inches thick to allow the opposing sides of the slot of the hollow, elongated tubular member to flex outwardly to allow the slot to open to accept the vasoocclusive device (Page 2, paragraph 14).
- wherein the hollow, elongated tubular member is formed from a polymer material with a durometer in the range of about 50D and 70D (page 4, paragraph 42). High-density polyethylene is a type of thermoplastic polymer and has a durometer of between 61D and 63D, falling in the disclosed range.

Diaz fails to teach a v-shape configured guide. However, Ahmed teaches the use of angled winged flanges in order to enhance guiding the element as the element is pushed through the opening (Col. 2 lines 68-70). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Diaz with the winged flanges as taught by Ahmed in order to enhance guiding the element as the element is pushed through the opening.

Ahmed fails to disclose the size of the interior angle between the wings, however, Ahmed does disclose that it should be at least thirty degrees, and further the angle used is sufficient to perform the function of a guide as illustrated in figure 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angles of the opening between 110 to 150 degrees, a working range as disclosed by the applicant, since the device as disclosed by Ahmed performs equally well as a guide without a specific angle range. Further, it has been held that where the general condition of the claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed 6/18/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- the sheath of Diaz does not remain attached to a segment of the flexible pusher member

- the newly amended claims including an embolic coil configured to be loaded into a microcatheter

The examiner respectfully disagrees with the applicant. The sheath is attached to the flexible pusher member at the proximal segment of the pusher member by using tab 24 (Fig. 1), the applicant does not state permanently fixed, only the term remain, the sheath of Diaz remains attached to a segment for a certain amount of time. The applicant is not distinctly claiming the microcatheter, the applicant is simply claiming functional language, which Diaz teaches.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3773

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773